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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WHISENANT, ETHAN C

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/27/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/536,841

Applicant(s)

FAN ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-40 is/are pending in the application.
- 4a) Of the above claim(s) 3-19 and 26-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The applicant's After Final Response with Notice of Appeal filed on 27 JUL 02 has been entered. The applicant's response was received on 03 SEP 02 and has been entered as paper no. 15. Following the entry of the amendment, Claim(s) 2-40 is/are pending with Claims 3-19 and 26-40 withdrawn as the result of a restriction requirement, leaving **Claims 2 and 20-25** under examination.

In view of the applicant's persuasive argument against the Finality of the previous Office Action (i.e. paper no. 14), the **Finality of the previous office action is hereby withdrawn**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 USC § 112- 2ND PARAGRAPH

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 2** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because the phrase "the nucleotide to be queried in the target polynucleotide sequence" on line 12 lacks proper antecedent basis.

35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

35 USC § 103

- 5.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 6.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

- 7.** **Claim(s) 2** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ugozzoli et al. (1992) in view of the Stratagene Catalog (1988).

Claim 2 is drawn to a kit comprising two components. To begin the kit is to comprise an array which itself comprises one or more oligonucleotide tags fixed to a solid substrate. Each oligo tag is to comprise a unique known arbitrary nucleotide sequence of sufficient length to hybridize to a locus specific tagged oligonucleotide. The second component making up the kit of Claim 2 is one or more locus-specific tagged oligos wherein each locus-specific tagged oligo has at its first (5') end a nucleotide sequence which is capable of hybridizing to the unique known arbitrary nucleotide sequence fixed on the array. At its second (3') end the locus-specific tagged oligo is to have a nucleotide sequence which is complementary to a target polynucleotide in a sample wherein the last nucleotide on the 3' end of the locus-specific tagged oligo is capable of hybridizing exactly one nucleotide before the nucleotide to be queried in the target polynucleotide.

Ugozzoli et al. teach an assay which utilizes the two components of the kit claimed in Claim 2. See for example Figure 1. Ugozzoli et al. do not teach a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the teachings of Ugozzoli et al. with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method taught by Ugozzoli et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

Claim Rejections under 35 USC § 102/103

8. Claim(s) 20 is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ugozzoli et al. (1992).

Ugozzoli et al. teach a set of primers comprising all of the limitations of Claim 20 except these authors do not explicitly teach that the set of primers is to be used determining a ratio of nucleotides present at a polymorphic locus. However, the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

ADDITIONAL CLAIM REJECTIONS UNDER 35 USC § 103

9. Claim(s) 21-24 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ugozzoli et al. (1992) as applied against Claim 1 above and further in view of the Stratagene Catalog (1988) and Shumaker et al. (1996).

Claim 21 is drawn to a kit comprising in a single container two or more of the sets of

primers of Claim 20 and at least two labeled ddNTPs each of which is distinctly labeled. Ugozzoli et al. in view Stratagene Catalog reasonably suggest a kit comprising a single set of oligo primer comprising the structure of Claim 20 as argued above. These authors do not however, teach a second set of oligo primers or the use of distinctly labeled ddNTPs. However, Shumaker et al. do teach a second set of oligo primers useful for genotyping the human HPRT gene, as well as the use of distinctly labeled ddNTPs to detect mutations/polymorphisms. In view of the fact that multiplexing was well known in the art at the time of the invention as evidenced by Shumaker et al., see for example p.347, 2nd Column under the heading "Gel-based Assay", it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Ugozzoli et al. in view Stratagene Catalog with the teachings of Shumaker et al in order to arrive at the claimed invention. The ordinary artisan would have been motivated to make this modification in order to take advantage of the efficiency afforded by multiplexing and analyzing multiple different polymorphic loci in a single assay or at the least simultaneously in separate assays. In addition, the ordinary artisan would have been motivated to make the modification recited above in order to eliminate the use of the dangerous radioactive reagents taught by Ugozzoli by using instead the fluorescently labeled ddNTPs of Shumaker et al.

Claim 23 is drawn to an embodiment of Claim 22 wherein solid support is an oligonucleotide array.

Shumaker et al. teach this limitation, see for example Figure 4.

Claim 24 is drawn to an embodiment of Claim 22 wherein solid support is bead.

Shumaker et al. teach this limitation, see for example p.347-348, under the heading "Gel-based Assay".

10. Claim(s) 25 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ugozzoli et al. (1992) in view of the Stratagene Catalog (1988) and Shumaker et al. (1996) as applied above and further in view of Mitsuhashi et al. [US 6,251,247 (2001)].

Claim 25 is drawn to an embodiment of Claim 22 wherein solid support is a microtiter plate.

Ugozzoli et al. in view of the Stratagene Catalog and Shumaker et al. teach all of the limitations of Claim 25 except these authors do not teach using a microtiter plate as a solid support. However, as evidenced by Mitsuhashi et al. the use of microtiter plates as a solid support for oligonucleotides was well known art the time of the invention. The substitution of one well known reagent with known properties for a second well known reagent with known properties is routine in the art, absent an unexpected result. As


regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

CONCLUSION

11. Claim(s) 2 and 20-25 is/are rejected and/or objected to for the reason(s) set forth above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



ETHAN C. WHISENANT
PRIMARY EXAMINER